

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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May 18, 2006

Date of Deposit

Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER ON/4-33289A
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/565,453
INTERNATIONAL APPLICATION NO. PCT/EP2004/008107	INTERNATIONAL FILING DATE 20 July 2004 (20.07.04)	PRIORITY DATE CLAIMED 21 July 2003 (21.07.03)	
TITLE OF INVENTION COMBINATIONS OF A CATHEPSIN K INHIBITOR AND A BISPHOSPHONATE IN THE TREATMENT OF BONE METASTASIS, TUMOR GROWTH AND TUMOR-INDUCED BONE LOSS			
APPLICANT(S) FOR DO/EO/US ZIMMERMANN ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 16. below concern document(s) or information included.**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Copy of Notification of Missing Requirements

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/565,453</b>		INTERNATIONAL APPLICATION NO. <b>PCT/EP2004/008107</b>		ATTORNEY'S DOCKET NUMBER <b>ON/4-33289A</b>	
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The following fees are submitted:				<b>CALCULATIONS</b> PTO USE ONLY	
21.	Basic national fee. ....	\$			
22.	Examination Fee				
	If International preliminary examination report was prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) .....	\$			
	All other situations. ....	\$			
23.	Search fee				
	If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. ....	\$			
	If International Search Report was prepared and provided to the Office. . .	\$			
	All other situations. ....	\$			
<b>TOTAL OF 21, 22 AND 23 =</b>			\$	0	

Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		X \$ 250	\$	
Surcharge of \$130 for furnishing the oath of declaration later than <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	130
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		X \$ 50	\$	
Independent claims	- 3 =		X \$ 200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	130
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
<b>SUBTOTAL =</b>				\$	130
Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$	130
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$	130

05/22/2006 GFREY1 00000139 190134 10565453 01 FC: 1517 130.00 DA	Amount to be: refunded \$ charged \$
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a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.

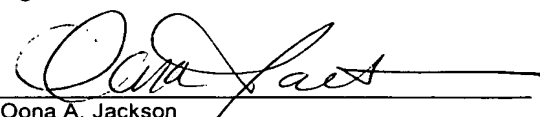
b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A duplicate copy of this form is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080

  
 Oona A. Jackson  
Attorney for Applicants  
Reg. No. 48,152  
(862) 778-7852



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/565,453	Zimmermann	ON/4-332894

INTERNATIONAL APPLICATION NO.
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PCT/EP04/08107

I.A. FILING DATE	PRIORITY DATE
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07/20/2004

07/21/2003

001095  
NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

CONFIRMATION NO. 9886

371 FORMALITIES LETTER



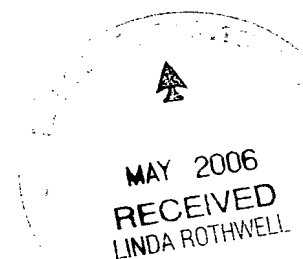
\*OC000000018671281\*

Date Mailed: 05/03/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/20/2006
- English Translation of the IA filed on 01/20/2006
- Copy of the International Search Report filed on 01/20/2006
- Preliminary Amendments filed on 01/20/2006
- Oath or Declaration filed on 01/20/2006
- Request for Immediate Examination filed on 01/20/2006
- U.S. Basic National Fees filed on 01/20/2006
- Priority Documents filed on 01/20/2006



The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/565,453	PCT/EP04/08107	ON/4-332894